Medical Device Accessories: Defining Accessories and Classification Pathway for New Accessory Types

Draft Guidance for Industry and Food and Drug Administration Staff

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For questions regarding this document, contact Mr. Sugato De at (301) 796-6270. For questions about this document concerning devices regulated by CBER, contact CBER's Office of Communication, Outreach and Development (OCOD) at 1-800-835-4709 or 240-402-7800.





U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
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Preface

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

The Food and Drug Administration (FDA) developed this draft document to provide guidance to industry and FDA staff about the regulation of accessories to other medical devices. This guidance is intended to clarify and modify FDA's policy concerning the classification of accessories and to discuss the application of that policy to specific categories of devices that are commonly used as accessories to other medical devices. In addition, this guidance also encourages utilization of the *de novo* classification process under Section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to allow manufacturers and other parties to request risk-based classification of accessories of a new type (i.e., accessories of a type that has not been previously classified under the FD&C Act or approved in an application for premarket approval (PMA)).

The FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Throughout this guidance document, the terms "we," "us" and "our" refer to FDA staff from the Center for Devices and Radiological Health (CDRH) or the Center for Biologics Evaluation and Research (CBER) involved in the review and decision-making aspects of the accessory *de novo* classification process. "You" and "your" refer to the submitter of an accessory *de novo* and/or

related materials.

II. Background

FDA has jurisdiction over accessories because the definition of the term "device" provided in Section 201(h) of the FD&C Act defines "device" to include, among other things, an "accessory."

The term "device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is –

- (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them;
- (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- (3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

FDA has traditionally determined the classification of device accessories in one of two ways:

- First, by inclusion in the same classification as the parent device, which can be:
 - O (1) Through operation of 510(k) Premarket Notification clearance. In this case, the name of the classification regulation identifies only the parent device. However, FDA, through the 510(k) submission, finds accessories to the parent device to be substantially equivalent. These accessories are thus classified within the same risk-based classification as the parent device. Similarly, when the parent device classification regulation identifies only certain accessories, FDA may determine additional accessories to be classified under the regulation via the 510(k) submission process;
 - o (2) Through operation of PMA approval. Accessories to an approved Class III device may also be approved in a PMA, in which case they would remain in class III along with the parent device; or
 - o (3) By express inclusion in the classification regulation or order¹ for the parent device. In this case, the title of the classification regulation specifically cites the name of the parent device and corresponding accessories. These classification

¹ Prior to the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), FDA reclassified devices under Section 513(e) of the FD&C Act through rulemaking; FDASIA changed this to an order process.

regulations or orders typically place accessories in the same risk-based classification (e.g., Class I, II, or III) as the parent device but sometimes classify accessories into a different risk-based classification.

Second, by issuance of a unique, separate classification regulation or order for the accessory. In this case, FDA has determined that a classification regulation for a accessory should be separate from that of the corresponding parent device. This type of classification has traditionally been considered for accessory types that may be used with multiple parent devices or that have unique standalone functions.

The classification of accessory devices, as for non-accessory devices, should reflect the risks of the device when used as intended and the level of regulatory controls necessary to assure safety and effectiveness. Classifying an accessory in the same class as its parent device is appropriate when the accessory, when used as intended, meets the criteria for placement in that class. However, some accessories can have a lower risk profile than that of their parent device and, therefore, may warrant being regulated in a lower class. For example, an accessory to a Class III parent device may pose lower risk that could be mitigated through general controls or general and special controls and thus could be regulated as Class I or Class II.

Accordingly, FDA has developed this guidance to clarify how its risk- and regulatory control-based framework applies to accessory devices and to encourage manufacturers and other parties to utilize the de novo classification process under Section 513(f)(2) of the FD&C Act to request risk-based classifications of accessories of a new type. This process provides a pathway to Class I or Class II classification for accessories for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

III. Scope

This guidance document clarifies what FDA intends to consider an "accessory" and clarifies how FDA's risk-based framework for classification applies to accessories to other medical devices. The considerations for determining applicable risk apply to all accessories.

In addition, this guidance describes use of the *de novo* classification process to classify accessories of a new type under Section 513(f)(2) of the FD&C Act. Accessories within a type of device that already has been classified by regulation or order, or has received PMA approval are not appropriate for classification through the de novo process.² Manufacturers of such devices and other interested parties may seek reclassification³ or exemption from the requirement to submit a

² See "New Section 518(f)(2) - Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff," February 19, 1998, available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Guidance Documents/ucm080195.htm. FDA proposed new thinking on de novo classification in its draft guidance entitled "De Novo Classification Process (Evaluation of Automatic Class III Designation)," on August 14, 2014, available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/ GuidanceDocuments/ UCM273903.pdf. This draft guidance is not final nor in effect at this time.

³ See Section 513(e) and Section 513(f)(3) of the FD&C Act.

510(k) report⁴ under applicable sections of the FD&C Act. While the general principles described in this guidance document for the risk-based regulation of accessories apply to reclassifications under Sections 513(e) and (f)(3), this guidance focuses on the application of these principles in the *de novo* classification process for the classification of accessories of a new type under Section 513(f)(2).

IV. Definitions⁵

Accessory: A device that is intended to support, supplement, and/or augment the performance of one or more parent devices.

Parent Device: A finished device whose performance is supported, supplemented, and/or augmented by one or more accessories.

V. Accessory Classification Policy

The policy governing the classification of accessories is subject to the same risk- and regulatory control-based scheme that FDA uses to classify all medical devices. The risks of an accessory are the risks that it presents when used with the corresponding parent device as intended. In order to classify an accessory, FDA addresses the following two questions:

- 1. Is the article an accessory?
- 2. What is the risk of the accessory when used as intended and what level of regulatory controls are necessary to provide a reasonable assurance of its safety and effectiveness?

The answers to these two questions inform the risk- and regulatory control-based classification of a potential accessory pursuant to the criteria at Section 513(a)(1) of the FD&C Act. Individual accessories may either be classified pursuant to the same regulation of a corresponding parent device or be regulated independently. The following subsections provide further detail in the analysis of these steps and describe accessory classification through the *de novo* process applicable to new types of accessories.

A. Is the article an accessory?

The accessory classification process begins with the analysis of whether the article under consideration is an accessory as defined in this guidance document. We consider an accessory as an article that:

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⁴ See Section 510(m) of the FD&C Act.

⁵ A specific article may meet one or more of the definitions in this section depending on its stated intended use. The policy described in this document is applicable only if we consider an article to be an accessory as described in this document.

1. Is intended for use with one or more parent devices.

Whether an article is intended for use with a parent device will generally be determined by the labeling and promotional materials for the potential accessory device (rather than by the labeling and promotional materials for the parent device). If labeling, promotional materials, or other evidence of intended use demonstrate that an article is intended for use with a device, whether a particular brand or a device type, the article is an accessory, and thus a "device" under section 201(h) of the FD&C Act.

It is important to note that articles that do not meet the definition of an accessory will not be treated as accessories simply because they may be used in conjunction with a device. For example, a mobile phone that is used as a general platform for applications that include mobile medical applications that are medical devices, or an off-the-shelf computer monitor used to display medical data would not be considered accessories unless they are intended for use with such devices.

2. <u>Is intended to support, supplement, and/or augment the performance of</u> one or more parent devices.

A device *supports* the performance of a parent device by enabling or facilitating that device to perform according to its intended use. For example, a rechargeable battery that is intended to operate when paired with an automated external defibrillator (AED) supports an AED by enabling it to defibrillate. In this case, the accessory is necessary to enable the parent device to meet its intended use. An infusion pump stand also supports the intended use of a parent device (an infusion pump) by holding medications or liquids and other infusion accessories firmly, at an appropriate height, and in convenient reach of the patient or caregiver. In this case, the parent device can perform its intended use without the accessory, but the accessory nonetheless supports the performance of the device.

A device *supplements* the performance of a parent device if it adds a new function or a new way of using the parent device, without changing the intended use of the parent device. For example, a pulse oximeter allows a multiparameter monitor to display oxygen saturation but does not change its intended use, which is to record and display multiple physiological parameters. Similarly, a new balloon catheter used to insert an already approved transcatheter heart valve into a smaller diseased artery supplements the parent device's intended use. The balloon catheter supplements the intended use of the transcatheter heart valve by expanding the population of patients who can receive the parent device to those with smaller diameter arteries, such as

women.

A device *augments* the performance of a parent device by enabling the device to perform its intended use more safely or effectively. *Augments* includes improving the performance of a parent device by enabling it to perform more quickly or improving usability or convenience for the device user. For example, a guidewire augments the performance of a bone-cutting instrument by increasing precision of the parent device and reducing the risk to the patient. Similarly, tools for the placement of an implantable nerve stimulator according to its intended use augment the performance of the stimulator by facilitating successful placement.

In practice, the distinctions among devices that support, supplement, or augment parent devices are subtle and many devices that meet the definition of an accessory may do more than one of these things. Thus, if the device is intended to support, supplement, *and/or* augment the performance of one or more parent devices, we will consider the device to be an accessory.

B. What are the risks of the accessory when used as intended with the parent device(s) and what regulatory controls are necessary to provide a reasonable assurance of its safety and effectiveness?

Under the policy described in this guidance, FDA intends to determine the risk of accessories and the controls necessary to provide a reasonable assurance of their safety and effectiveness according to their intended use in the same manner that is used to determine such for devices that are not accessories. Because accessories are intended to be used with and to support, supplement, and/or augment one or more parent devices, FDA will determine the risks of accessories when used, as intended, with the parent device type. Determining the risks of accessories according to their use with parent devices does not mean that all risks of a parent device are imputed to the accessory; the risk profile of an accessory can differ significantly from that of the parent device, warranting differences in regulatory classification. In determining the classification of an accessory, FDA will evaluate the risks imposed by the accessory's impact on the parent device and any unique risks of the accessory independent of its parent device. As with the classification of any other device, the types of regulatory controls necessary to control the risks will determine the regulatory class for accessories.

C. Accessory Classification through the *De Novo* Process

FDA encourages manufacturers and other parties (hereafter "submitter") to utilize the *de novo* classification process⁶ in Section 513(f)(2) of the FD&C Act to request risk-based

⁶ See "New Section 518(f)(2) - Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff," February 19, 1998, available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Guidance

classifications of new types of accessories. This process provides a pathway to Class I or Class II classification for accessories for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there are no legally marketed predicate device.

In accordance with Section 513(f)(2), a submitter may submit a *de novo* requesting FDA to make a classification determination for the accessory according to the criteria in Section 513(a)(1) of the FD&C Act. The *de novo* must include a description of the device and detailed information and reasons for any recommended classification (see section 513(f)(2)(A)(v) of the FD&C Act⁷). Please refer to Appendix 1 for the information FDA recommends be submitted in a *de novo* request for a new type of accessory.

FDA must make a classification determination for the device that is the subject of the *de novo* by written order within 120 days of the request (see Section 513(f)(2)(A)(iii) of the FD&C Act).

If the submitter demonstrates that the criteria in Section 513(a)(1)(A) or (B) of the FD&C Act are met (i.e., accessories for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness), FDA will grant the *de novo*, which classifies the new accessory (and accessory type) in Class I or Class II. The accessory may then be marketed immediately and serve as a predicate device for future 510(k) premarket notifications. FDA will publish a notice in the Federal Register announcing the classification and the controls necessary to provide reasonable assurance of safety and effectiveness. If the *de novo* is declined⁸, the accessory remains in Class III⁹ and may not be marketed.

<u>Documents/ucm080195.htm.</u> FDA proposed new thinking on *de novo* classification in its draft guidance entitled "<u>De Novo Classification Process (Evaluation of Automatic Class III Designation)," issued on August 14, 2014, available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ UCM273903.pdf. This draft guidance is not final nor is it in effect at this time.</u>

⁷ See also Section 513(f)(2)(A)(v) of the FD&C Act, which states: "The person submitting the request for classification…may recommend to the Secretary a classification for the device and shall, if recommending classification in class II, include in the request an initial draft proposal for applicable special controls, as described in subsection (a)(1)(B), that are necessary, in conjunction with general controls, to provide reasonable assurance of safety and effectiveness and a description of how the special controls provide such assurance. Any such request shall describe the device and provide detailed information and reasons for the recommended classification."

⁸ A *de novo* could be declined if the performance data provided in the *de novo* request do not support that general controls or general and special controls can appropriately mitigate identified risks to health for the device to provide a reasonable assurance of safety and effectiveness.

⁹ Devices of a new type that FDA has not previously classified based on the criteria at Section 513(a)(1) of the FD&C Act are "automatically" or "statutorily" classified into class III by operation of section 513(f)(1) of the FD&C Act, regardless of the level of risk they pose or the ability of general controls or general and special controls to provide a reasonable assurance of safety and effectiveness. This is because, by definition, a new type of device would not be within a type that was on the market before the date of the enactment of the Medical Device Amendments (i.e., May 28, 1976) or that has since been classified into class I or class II.

Appendix 1 – Request for Accessory De Novo Classification

Manufacturers or other interested parties may seek a decision by the FDA on the appropriate risk-based classification of a new type of accessory by filing a *de novo* request (hereafter a "*de novo*") under section 513(f)(2) of the FD&C Act. This process is also known as the *de novo* classification process.¹⁰

In order to streamline the submission and evaluation of the accessory *de novo* so that only information necessary to assess accessory safety and effectiveness is submitted and reviewed, we recommend that the following information be provided:

- Clear identification as a *de novo* request for a new accessory device;
- Device Information and Summary:
 - A description of the relevant parent device(s);
 - A description of the ability for the accessory to be compatible with a specific parent device or a class of devices;
 - A description of the technical characteristics of the accessory, which ensure compatibility with a specific parent device or a class of devices;
- Identification of products to which the accessory is compatible, including model number, connector type, etc.;
- Classification summary and recommendation:
 - The classification summary should include a rationale for why the accessory device does not fit within any identified classification for the parent device(s);
- An identification of the risks to health presented by the accessory device and proposed mitigation measures;
- Proposed controls:
 - For class II devices, list of general and special controls that sufficiently mitigate the risks to health, including compatibility of the accessory device with parent device, and applicability of 510(k) for future devices¹¹ and a description of how the proposed special controls will provide a reasonable assurance of safety and effectiveness for the accessory device
 - For class I devices, an identification of how the application of general controls only would sufficiently mitigate the risks to health;
- Summary of the performance data supporting the *de novo*:

¹⁰ See "New Section 518(f)(2) - Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff," February 19, 1998, available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080195.htm. On August 14, 2014, FDA proposed new thinking on *de novo* classification in its draft guidance entitled "*De Novo* Classification Process (Evaluation of Automatic Class III Designation)," available at http://www.fda.gov/downloads/Medical Devices/DeviceRegulationandGuidance/GuidanceDocuments/UCM273903.pdf.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080198.htm.

¹¹ For more information on factors FDA may consider for exemption from premarket notification, please refer to the guidance entitled "<u>Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,</u>" available at

- Reference to all reasonably known relevant data and information, including new information, about the accessory device and/or in combination with the parent device(s), whether favorable or unfavorable to the proposed classification; and
- Labeling of the accessory with adequate instructions for use with the parent device(s):
 - Include labeling instructions to address compatibility of the new accessory device and the parent device(s), including any relevant performance data to support compatibility; and
 - Include relevant technical characteristics of the accessory.

In preparing a *de novo* request for a new accessory device, we suggest you review publicly posted information, including decision summary documents, for recently granted CDRH *de novos* available on our website at

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm232269.htm.

In an effort to further streamline and facilitate FDA's review of your accessory *de novo* classification request, we recommend that you provide a draft executive summary document with the following information:

- Administrative information,
- Proposed identification language for a new classification regulation or order;
- Summary of the accessory device, including a detailed description of the accessory, including any necessary technical characteristics and compatibility information with the parent device(s);
- Summary of the performance data to support the proposed classification recommendation:
- Risk and Mitigation Information: for class I accessory devices, an explanation of how general controls adequately mitigate any risks to health; for class II accessory devices, listing of the risks and mitigation measures, including the special controls necessary to mitigate the risks to health; and
- Benefit/Risk Considerations. 12

¹² For information on benefit-risk determinations and factors considered, please see FDA guidance entitled "<u>Guidance for Industry and Food and Drug Administration Staff</u> - <u>Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and De Novo Classifications</u>," <u>available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm267829.htm.</u>